

Statutory Approvals Committee – minutes

Centre 0327 (Boston Place)

Special Direction application to export embryos to the USA for use in treatment

Thursday, 28 November 2019

HFEA, Spey Meeting Room 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Tony Rutherford	
Members of the Executive	Moya Berry Catherine Burwood	Committee Secretary Licensing Manager
Legal Adviser	Eve Piffaretti	Blake Morgan - LLP

Declarations of interest

- Members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members
- General Directions 0001 (2015)
- General Directions 0006 (2018)
- General Directions 0013 (2018)
- HFEA Standing Orders (2018)
- Special Directions Decision Tree (2018)

The following papers were considered by the committee

- Executive Summary
 - Special Directions Application Form
 - Further information Form
 - Letter from the proposed receiving clinic confirming acceptance of the embryos.
 - Supporting Statement provided by the center
 - Statement from the couple with a letter from the GP
 - Narrative from the legal team regarding the case
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1. Background

- 1.1.** The Person Responsible (PR) at Centre 0327 (the applicant) has applied for a Special Direction for the export of seven embryos from Boston Place to San Diego Fertility Center, California, United States of America.
- 1.2.** The committee noted that since 2005, the couple had been aware that their chances of being able to conceive naturally was likely to be compromised due to the woman's premature infertility. The couple therefore committed to the process of freezing fertilised embryos and have seven embryos, currently in storage at Boston Place. The embryos were originally created and frozen at another licensed centre on the 29 October 2007, where the couple consented to five years storage, the maximum storage period available at that time. The couple consented to a further five years storage on the 1 June 2012 with consent to storage expiring on the 28 November 2017.
- 1.3.** The couple's embryos were transferred to Boston Place Clinic on the 26 January 2017. However, during an audit of consent documents, the storage date for the embryos was incorrectly calculated to 28 November 2018. The couple were notified and signed Extension to Storage (ES) consent forms on the 29 August 2018 where they consented to a 20-year storage.
- 1.6.** The committee noted that due to family crises beyond their control, the patient couple had to delay their own fertility treatment to support members of their extended families. The couple now wish to export their embryos abroad, to use in their fertility treatment and have identified San Diego Fertility Center in California as the clinic they wish to export their embryos.
- 1.7.** The committee noted the embryos have been created by the patient couple's own gametes.
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2. Consideration of application

Application

- 2.1.** The committee considered the application, which included an executive summary, a Special Direction application form and Further Information form.
- 2.2.** The committee noted that the Human Fertilisation and Embryology Act (as amended) permits the Authority to issue directions to allow exports of gametes or embryos to countries outside of the United Kingdom. Furthermore, the committee noted that in relation to the import and export of gametes and embryos outside of the European Economic Area and Gibraltar, movement can be permitted without the need for a Special Direction if the conditions outlined in General Directions 0006 are satisfied.
- 2.3.** The committee noted that this application for a Special Direction is being made as the centre stated that it is unable to export the embryos to San Diego Fertility Center, California, under General Directions 0006, since the following requirements of Schedule 4 are not met:

1(i) the remaining term of the relevant storage period for the gametes or embryos, as provided for in section 14 (3) or (4) or by Regulations made under section 15 (5) of the HFE Act 1990

amended, and the period for which the gametes and embryos may remain stored in accordance with the consent(s) of the relevant gamete provider(s), are not less than 6 months from the date on which they are to be exported.

- 2.4.** The committee noted the information that had been provided to support the Special Direction application. This included a letter from San Diego Fertility Center, California, to accept seven embryos for the purpose for use in the patient couple's own fertility treatment.

3. Decision

- 3.1.** The committee noted the advice of its legal adviser who confirmed The HFEA (Statutory Storage Period for Embryos and Gametes) Regulations 2009/1582 ('the Regulations') came into force during the initial five-year storage period the couple consented to. The applicable provision (regulation 5) provides that, where an embryo was first placed in storage with the original consent period of five years and the storage has not expired on the date the Regulations came into force (which in this case it had not), the maximum storage period for the embryo in question shall be:

- (a) ten years from the date the embryos were first placed in storage; or
- (b) ten years after the date of the most recent written opinion from a registered medical practitioner that either the patient or her partner is prematurely infertile or is likely to become prematurely infertile.

- 3.2.** The committee noted that a letter dated the 17 September 2012 from the couple's GP expressed the professional opinion that the female patient was prematurely infertile at that time. This was a written opinion from a registered medical practitioner provided after the coming into force of the Regulations and within the relevant period (i.e. within 5 years from the date on which the embryos were first placed in storage). The written opinion, therefore, satisfied the requirements of regulation 5. Accordingly, the effect of the opinion was to extend the maximum storage period to 16 September 2022 (i.e. 10 years from the date of the opinion).

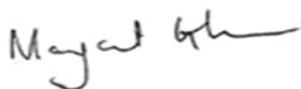
- 3.3.** The committee agreed, based on the advice of its legal adviser and the information presented in the application, that the embryos are lawfully stored in the UK. Accordingly, there was no requirement for the committee to issue a Special Direction for Centre 0327, to export from Boston Place, 16-20 Boston Place, London NW1 6ER, United Kingdom to San Diego Fertility Center, 11425 El Camino Real, San Diego California 92130, United States of America, seven embryos for storage for use in treatment by a patient couple.

- 3.4.** The committee noted that, although there is no requirement to export the embryos from the United Kingdom in order for the patient couple to use them in treatment services, should the patient couple wish to do so, there is no obstacle to the embryos being exported under General Directions.

4. Chairs signature

- 4.1.** I confirm this is a true and accurate record of the meeting.

Signature



Name

Margaret Gilmore

Date

10 December 2019

